YA HORNG ELECTRONIC CO., LTD.

No.35, Shalun, Anding Dist., Tainan City 745,Taiwan (R.O.C.)

TEL: 886-6-5932201~8 FAX: 886-6-5930030 web:www.yahorng.com e-mail: rdsafety@yahorng.com

SUMMARY OF SAFETY AND EFFECTIVENESS

(According to 21 CFR 807.92)

AUG 17 2012

" 510(k) Summary for K121025 "

Submitter's Name:	YA HORNG Electronic Co., Ltd.
Address:	***No. 35, Zsha Lun, Jon Zsha Village, Antin District, Tainan, 74555, Taiwan, ROC***
Telephone:	886-6-5932201
FAX:	886-6-5930030
Contact Person:	Dr. Jen, Ke-Min
Date Summary Prepared:	March 23, 2012
Proprietary Name:	Upper Arm Blood Pressure Monitor, model BP-700NW and Bluetooth Transmission BP-700W
Common Name:	BLOOD PRESSURE MONITOR
Classification Name:	NON-INVASIVE BLOOD-PRESSURE MEASUREMENT SYSTEM (per 21CFR section 870.1130)
Device Class:	Class II (performance standards)
Specialty:	CARDIOVASCULAR
Product code:	DXN
Legally Marketed (Predicate) Device :	• YA HORNG Digital Upper Arm Blood Pressure Monitor BP-700, BP-700T, BP-700U, BP-700B, BP-700TB, BP-700UB, and BP-700TUB (K090058) • A & D Medical UA-767BT Digital Blood Pressure Monitor (K040371)

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Description of the new device: (Same as the predicate devices)

YA HORNG Upper Arm Blood Pressure Monitor, model BP-700NW and Bluetooth Transmission BP-700W use the Oscillometric method to measure the blood pressure. The Oscillometric method is adopted clinically to measure the blood pressure recently. It is not needed to use the stethoscope, as in the traditional measuring method, to monitor the Korotkov sound when deciding the systolic or diastolic pressure. The Oscillometric method senses the vibrating signal via the closed air pipe system and utilizes the microcomputer to automatically sense the characteristics of the pulse signal. Through simple calculation, the reading can reflect the accurate real blood pressure, and the systolic pressure is defined as the pressure when the cuff pressure oscillating amplitude begins to increase and the diastolic pressure as the pressure when the cuff pressure oscillating amplitude stops decreasing.

Technological Characteristics of our new device compared to the predicate device:

The technological characteristics of YA HORNG Upper Arm Blood Pressure Monitor, model BP-700NW and Bluetooth Transmission BP-700W are substantially equivalent to YA HORNG Digital Upper Arm Blood Pressure Monitor BP-700, BP-700T, BP-700U, BP-700B, BP-700TB, BP-700UB, BP-700TUB (K090058). There is the same Owner, YA HORNG Electronic Co., Ltd., which FDA owner number is 9040892. Especially, there are the same design specifications, the same form and intended to be used in the same manner that means the new devices are same as the predicate devices.

Besides, the subject device BP-700W and the other predicate device A & D Medical UA-767BT Digital Blood Pressure Monitor (K040371) are also with the wireless communication function connect to the PC for record archiving and printing purposes.

The major differences from the predicate devices and the subject devices as below:

- The predicate devices: BP-700U, BP-700UB, and BP-700TUB (K090058), software in the PC for record archiving and printing purposes.

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- The subject device BP-700W: replace the USB cable to transfer data of the BP-700W with Bluetooth module for the wireless communication function connect to PC for record archiving and printing purposes.
- The predicate device: A & D Medical UA-767BT Digital Blood Pressure Monitor (K040371) and subject device BP-700W are also with the wireless communication function, and only has the different dimensions and the conditions of the operation and storage. Besides, they use the different size of cuffs.
- The subject device BP-700NW is identical for the BP-700W; and only does not with the wireless communication function.

Thus there are substantially equivalent.

Test Summary:

1. **ELECTRIC SAFETY, EMC and FCC test reports,**

General safety	*IEC/EN 60601-1:2007*	***PASS***
	EN 1060-1:2009, EN 1060-3:2009	***PASS***
EMC conformity	*IEC/EN 60601-1-2: 2010*	***PASS***
FCC conformity	*ANSI C63.4: 2003*	***PASS***
	FCC 47 part 15 subject B class B	***PASS***
ERM conformity	*EN 30148-1:2008, EN 30148-17:2009*	***PASS***
RF conformity	*EN 300328:2006*	***PASS***

2. **WOVEN COTTON SHEETING:** (Same as the predicate devices K090058)
   Uses the 510K Blood-Pressure Cuff: YA HORNG Blood-Pressure Cuff (K051539).

3. **PERFORMANCE & CLINICAL TEST**
   ANSI / AAMI SP 10: 2002
   ANSI / AAMI ISO 81060-2:2009
   EN 1060-4:2004

YA HORNG Electronic Co. Ltd. believes this information and referred document to be sufficient for the FDA to find our proposed device substantially equivalent to the predicate product and other products currently in distribution.

Dr. Jen, Ke-Min
official correspondent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 17 2012

Ya Horng Electronic Co., Ltd.
c/o Dr. Ke-Min Jen
ROC Chinese-European Industrial Research Society
No. 58, Fu-Chiun St.
Hsin-Chu City, 30067
Taiwan, ROC

Re: K121025
Trade/Device Names: 1) Ya Horng Upper Arm Blood Pressure Monitor BP-700NW; and
2) Ya Horng Upper Arm Blood Pressure Monitor, Bluetooth Transmission BP-700W
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: July 16, 2012
Received: July 24, 2012

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K121025**

Device Name: YA HORNG ELECTRONIC CO., LTD.

Upper Arm Blood Pressure Monitor BP-700NW,

Upper Arm Blood Pressure Monitor, Bluetooth Transmission BP-700W

- ***Indications for use:***

The YA HORNG Upper Arm Blood Pressure Monitor, model BP-700NW and Bluetooth Transmission BP-700W are noninvasive blood pressure measurement systems intended to measure the systolic and diastolic blood pressures and pulse rate of an adult individual, over age 18, at home by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to be 9.0"~13.0" for Arm type.

※ Optional model: BP-700W with Bluetooth module for the wireless communication function connects to the PC for record archiving and printing purposes.

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121025